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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,739	11/30/1999	DIRK JAGER	LUD-5615	9448
24972	7590	01/07/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			NICKOL, GARY B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 01/07/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/451,739

Applicant(s)

JAGER ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 81-84, 86, 88, 90, 92 and 94 is/are allowed.
- 6) ☒ Claim(s) 80, 85, 87, 89, 91, 93 and 95-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence error report.

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Response to Amendment

The Amendment filed August 14, 2003 (Paper No. 25) in response to the Office Action of May 14, 2003 is acknowledged and has been entered.

Claims 80-97 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Sequence Listing Errors/Summary

A non-final rejection was mailed to applicants on 05-14-03 (Paper No. 25) which included an objection to the specification. Specifically, it was noted that SEQ ID NO:11 on page 11 differed by one nucleotide from the as-filed sequence listing. Applicant's response (Paper No. 25, page 4) included a replacement sequence listing wherein the last nucleotide of SEQ ID NO:11 in the sequence listing was changed to a "C" correcting the discrepancy and now is completely identical to SEQ ID NO:11 disclosed on page 11. Hence, no new matter was added to the specification. However, the replacement sequence listing on the computer readable file (CRF) contained unrelated errors and a notice of non-responsiveness including a copy of the sequence errors was mailed to Applicant's on 09-12-03. In response (Paper No. 27), Applicants attempted to correct the sequence with a replacement written sequence listing accompanied by a new CRF. Applicants further noted that (Paper No. 27, page 2) there was no requirement in the original

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office action of 05-14-03 to comply with the sequence rules and that applicants could not have failed to comply. This argument has been considered and is found persuasive to the extent that the amendments of Paper No. 25 will now be considered. Further, in order to promote compact prosecution, the issues relating to the errors in the CRF will be maintained as objections.

New Objections:

The replacement sequence listing and accompanied CRF filed 09-22-03 (Paper No. 27) is objected to because the diskette contained new errors. A copy of the most current raw sequence listing error report (preformed 09-26-03) is attached with this Action.

Rejections Maintained:

Claims 80, 85, 87, 89, 91, 93, and 95-97 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth previously, the written description in this case only sets forth an isolated nucleic acid molecule comprising SEQ 15 and or the "complete" complement thereof.

Applicant's amendments to the claims now include *highly* stringent conditions under high temperature and further label the nucleic acid molecules as those that encode a cancer associated antigen. Applicants argue (Paper No. 25, page 6) that the rejection cannot be maintained because specific hybridization conditions are given, as is a function for the molecules claimed.

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Applicants further argue that Example 9 of the “Revised Interim Guidelines for Compliance with the Written Description Requirement” is clearly on point, and supports the amendment. This argument has been considered but is not found persuasive because labeling the encoded molecules, as “cancer associated” does not adequately define the “coding function” of the encompassed DNA. Example 9 of the revised guidelines (<http://www.uspto.gov/web/menu/written.pdf>) indicates that the genus of nucleic acids encompassed by the hybridization language must encode a protein with a “specific activity”. In fact, the language exemplified by Example 9 claims “an isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID: 1, wherein said nucleic acid encodes *a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity*”. Thus, because cancer-associated genes may have a wide range of specific activities and because the claims do not specifically define what that activity is, a person of skill in the art would not recognize from the disclosure that applicants were in possession of the genus of nucleic acids, all of which must hybridize with SEQ ID NO:15.

Applicants further argue (page 6) that the terminology in the claim reflects that found in the claims of US Patent Nos. 6,297,364 or 5,576,756. This argument has been considered but is not found persuasive, as the claims in these patents do not adequately reflect the claims in the current case, drawn to hybridizing polynucleotides. Appropriate parallel terminology, however, can be found in the claims of US Patent No. 6,500,942 or US Patent No. 6,255,470, complimentary copies of which are attached herein. Therefore, only an isolated nucleic acid molecule comprising SEQ ID NO: 15 and or the complete complement thereof meets the written

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description provision of 35 U.S.C. §112, first paragraph. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Allowable Subject Matter

Claims 81-84, 86, 88, 90, 92, 94 are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143.

The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
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GBN
January 7, 2004

Gary B. Nickol